(ii) *Indications for use.* Control of early mortality associated with *Escherichia coli* organisms susceptible to colistin.

(iii) *Limitations.* For subcutaneous injection in the neck of 1- to 3-day-old chickens. Not for use in laying hens producing eggs for human consumption. Do not use in turkeys. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 13123, Mar. 18, 1998]

§ 522.480 Repository corticotropin injection.

(a)(1) *Specifications.* The drug conforms to repository corticotropin injection U.S.P. It contains 40 or 80 U.S.C. (I.U.) units per cubic centimeter.

(2) *Sponsor.* See No. 037990 in § 510.600(c) of this chapter.

(3) *Special considerations.* The drug should be refrigerated. With prolonged use supplement daily diet with potassium chloride at one gram for small animals and from 5 to 10 grams for large animals.

(4) *Conditions of use.* (i) It is used as an intramuscular or subcutaneous injection in cattle and small animals for stimulation of the adrenal cortex where there is a general deficiency of corticotropin (ACTH). It is also a therapeutic agent for primary bovine ketosis.

(ii) It is administered to cattle initially at 200 to 600 units followed by a dose daily or every other day of 200 to 300 units and to small animals at one unit per pound of body weight to be repeated as indicated.

(iii) For use only by or on the order of a licensed veterinarian.

(b)(1) *Specifications.* The drug conforms to respository corticotropin injection U.S.P. It contains 40 or 80 U.S.P. units per milliliter.

(2) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) For intramuscular injection in dogs as a diagnostic aid to test for adrenal dysfunction. For intramuscular or subcutaneous injection in dogs and cats for stimulation of the adrenal cortex where there is a general deficiency of ACTH.

(ii) For diagnostic use: Administer at one unit per pound of body weight intramuscularly. For therapeutic use: Administer at one unit per pound of body weight intramuscularly or subcutaneously, initially, to be repeated as indicated.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c) *National Academy of Sciences/National Reserach Council (NAS/NRC) status.* The therapeutic indication for use has been reviewed by NAS/NRC and found to be effective. Applications for this use need not include effectiveness data as specified in § 514.111 of this chapter, but may require bioequivalency and safety information.

[40 FR 13858, Mar. 27, 1985, as amended at 50 FR 40966, Oct. 8, 1985; 53 FR 45760, Nov. 14, 1988; 68 FR 59881, Oct. 20, 2003]

§ 522.518 Cupric glycinate injection.

(a) *Specifications.* Each milliliter (mL) of sterile aqueous suspension contains 200 milligrams of cupric glycinate (equivalent to 60 milligrams of copper).

(b) *Sponsor.* See No. 049185 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 200 milligrams (1 mL) for calves 300 pounds and under; 400 milligrams (2 mL) for calves over 300 pounds and adult cattle.

(2) *Indications for use.* For beef calves and beef cattle for the prevention of copper deficiency, or when labeled for veterinary prescription use, for the prevention and/or treatment of copper deficiency alone or in association with molybdenum toxicity.

(3) *Limitations.* For subcutaneous use only; repeat dose in 3 months in young calves, in 6 months in cattle; discontinue use 30 days before treated animals are slaughtered for food use; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 20159, Apr. 3, 1981, as amended at 52 FR 7832, Mar. 13, 1987; 62 FR 28630, May 27, 1997]

§ 522.522 Danofloxacin.

(a) *Specifications.* Each milliliter of solution contains 180 milligrams (mg) danofloxacin as the mesylate salt.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §556.169 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount.* 6 mg per kilogram of body weight by subcutaneous injection. Treatment should be repeated approximately 48 hours following the first injection.

(2) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia (Pasteurella) haemolytica* and *Pasteurella multocida*.

(3) *Limitations.* Animals intended for human consumption should not be slaughtered within 4 days from the last treatment. Do not use in cattle intended for dairy production. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extra-label use of this drug in food-producing animals.

[67 FR 78972, Dec. 27, 2002]

§ 522.533 Deslorelin acetate.

(a) *Specifications.* Each implant contains 2.1 milligrams deslorelin acetate.

(b) *Sponsor.* See 064288 in §510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Horses and ponies*—(i) *Amount.* One implant per mare.

(ii) *Indications for use.* For inducing ovulation within 48 hours in estrous mares with an ovarian follicle greater than 30 millimiters in diameter. Follicular size should be determined by rectal palpation and/or ultrasonography prior to treatment.

(iii) *Limitations.* Administer subcutaneously in the neck. Not for use in horses or ponies intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 44383, Aug. 19, 1998]

§ 522.535 Desoxycorticosterone pivalate.

(a) *Specifications.* Each milliliter of sterile aqueous suspension contains 25 milligrams of desoxycorticosterone pivalate.

(b) *Sponsor.* See No. 058198 in §510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Dosage requirements are variable and must be individualized on the basis of the response of the patient to therapy. Initial dose of 1 milligram per pound (0.45 kilogram) of body weight every 25 days, intramuscularly. Usual dose is 0.75 to 1.0 milligram per pound of body weight every 21 to 30 days.

(ii) *Indications for use.* For use as replacement therapy for the mineralocorticoid deficit in dogs with primary adrenocortical insufficiency.

(iii) *Limitations.* For intramuscular use only. Do not use in pregnant dogs, dogs suffering from congestive heart disease, severe renal disease, or edema. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 13122, Mar. 18, 1998]

§ 522.536 Detomidine hydrochloride injection.

(a) *Specification.* Each milliliter of sterile aqueous solution contains 10 milligrams of detomidine hydrochloride.

(b) *Sponsor.* See 052483 in §510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* For sedation, analgesia, or sedation and analgesia: 20 or 40 micrograms per kilogram (0.2 or 0.4 milliliter per 100 kilogram or 220 pounds) by body weight, depending on depth and duration required.

(2) *Indication for use.* As a sedative and analgesic to facilitate minor surgical and diagnostic procedures in mature horses and yearlings.

(3) *Limitations.* For sedation administer intraveneously (IV) or intramuscularly (IM); for analgesia by IV; for both sedation and analgesia by IV. Do not use in horses with pre-existing atrioventricular or sinoauricular block, with severe coronary insufficiency, cerebrovascular disease, respiratory disease, or chronic renal failure. Do not use in breeding animals. Not for use in horses intended for food. Federal law restricts this drug to use